THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE SUBOXONE (BUPRENORPHINE HYDROCHLORIDE AND NALOXONE) ANTITRUST LITIGATION	**MDL NO. 2445**
THIS DOCUMENT RELATES TO:	**Master File No. 2:13-MD-2445-MSG**
All Actions	

MEMORANDUM OF LAW IN SUPPORT OF
DEFENDANTS' LOCAL CIVIL RULE 7.1(G) MOTION TO RECONSIDER

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

CASES

STATUTES

OTHER AUTHORITIES

INTRODUCTION

Reckitt Benckiser Pharmaceuticals, Inc. ("Reckitt") recognizes the consideration and care that went into this Court's 76-page opinion of December 3rd, resolving multiple and "relatively novel" issues of federal and state law raised by the motions to dismiss both class complaints. (Dkt. No. 97 at 18.) In bringing this narrowly focused motion, Reckitt does not "request that [the] court rethink a decision it has already made." *Drysdale v. Woerth*, 153 F. Supp. 2d 678, 682 (E.D. Pa. 2001). Instead, Reckitt requests reconsideration of certain issues under Local Civil Rule 7.1(g) because it appears that the Court overlooked three arguments raised in Reckitt's dispositive motions. On one of these issues, moreover, newly discovered and previously unavailable evidence subject to judicial notice (a report the FDA issued after the oral argument) facially contradicts one of plaintiffs' core allegations. Reconsideration is appropriate where "there were . . . legal issues properly presented but overlooked by the court" or where "new evidence, which was not previously available, has become available." *Blue Mountain Mushroom Co. v. Monterey Mushroom, Inc.*, 246 F. Supp. 2d 394, 398-99 (E.D. Pa. 2002) (quotation marks and citation omitted). Accordingly, Reckitt respectfully prays this Court to reconsider its December 3rd ruling in order to address these three issues.

First, concerning plaintiffs' citizen-petition claims, two independent grounds—one factual, one legal—urge reconsideration. Factually, new evidence subject to judicial notice contradicts any allegation "that the FDA violated 21 U.S.C. § 355(q)(1)(A)." (Dkt. No. 97 ['Op'n'] at 33.) Specifically, on November 17, 2014, the FDA submitted to Congress its *Sixth Annual Report on Delays in Approvals of Applications Related to Citizen Petitions*, a copy of which is attached as Exhibit A. This report established that only one petition—the Novartis petition discussed by the Court (Op'n at 33)—caused delay of any ANDA approvals in Fiscal Year 2013. (*See* Exh. A at 3.) In light of this new evidence, this Court should reconsider the

adequacy and plausibility of plaintiffs' allegations that the FDA may have delayed generic Suboxone ANDAs because of Reckitt's petition. Because there is no presumption that the FDA violated the statute, and no non-conclusory facts alleged to suggest that it happened *in this case*, this new contrary evidence renders the inference that the FDA did so implausible under *Bell Atlantic Corp. v. Twombly*. 550 U.S. 544, 570 (2007).

Legally, even if plaintiffs did plausibly allege the FDA's violation of 21 U.S.C. § 355(q)(1)(A), this Court's opinion did not address Reckitt's argument that any such violation would establish a supervening cause relieving Reckitt from liability. (*See* Dkt. No. 56-1 ['DP Mot.'] at 33 n.21; Dkt. No. 81 ['DP Reply'] at 21.) Settled Third Circuit law provides that the causal chain is severed when an independent government actor fails to follow proper procedures. *See, e.g.*, *Egervary v. Young*, 366 F.3d 238, 250-51 (3d Cir. 2004); *Mass. Sch. of Law at Andover, Inc. v. Am. Bar Ass'n*, 937 F. Supp. 435, 439 (E.D. Pa. 1996) ("[W]hen an antitrust-plaintiff's injury is proximately caused by the government, the government's action constitutes a supervening cause that breaks the chain of causation between an antitrust-defendant's action and any anticompetitive effect."), *aff'd,* 107 F.3d 1026, 1035-41 (3d Cir. 1998).

This Court should grant Reckitt's motion, consider both the FDA's report and the causation argument, and dismiss Counts IV and V.

Second, the Court granted Reckitt's motion to dismiss the Direct Purchaser Plaintiffs' claims against Reckitt Benckiser Group, plc ("RBG"), but denied the same motion as to the End-Payor Plaintiffs, concluding that their allegations were "sufficient to establish [RBG's] role in the alleged scheme." (Op'n at 74.) But Reckitt's argument was not directed only at the failure to allege RBG's *role*. Rather, Reckitt also contended that the end-payors had failed to allege RBG's *market power*. (*See* Dkt. No. 57-1 ('EP Mot.') at 38-39 ("[T]his Court's precedent . . .

has dismissed antitrust complaints . . . alleging that a group of distinct corporate entities shared *market power*." (emphasis added)); Dkt. No. 82 ('EP Reply') at 24 ("[N]one of the allegations relied on by plaintiffs relate to *market power*." (emphasis added)).) Market power is, of course, a necessary element for any § 2 claim other than conspiracy to monopolize. (*See* Op'n at 12 (quoting *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966)).) Plaintiffs have not and cannot allege a conspiracy between RBG and its corporate affiliates, *see, e.g.*, *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 776-77 (1984), so market power is a necessary element of the end-payors' § 2 claims against RBG. But the end-payors have not alleged that RBG has market power. RBG does not sell any co-formulated buprenorphine and naloxone product in the United States. Thus, this Court should grant Reckitt's motion to reconsider, consider the market power argument, and dismiss Reckitt's corporate affiliate RBG from this case.

Third, the Court agreed with the major premise of Reckitt's product-hopping argument, that "introducing a new product on the market, whether it is a superior product or not, does not, by itself constitute exclusionary conduct." (Op'n at 18.) Nonetheless, the Court declined to dismiss Count II because of Reckitt's alleged "'coercive' measures," namely Reckitt's statements to the market regarding its intention to withdraw tablets due to safety concerns. (*Id.* at 19.) In so doing, however, the Court did not consider the "strong presumption that statements by competitors have a '*de minimis*' effect on competition." (DP Reply at 19; *see id.* at 12 & n.6 (cross-referencing this argument); DP Mot. at 18.) Applying that presumption here is fatal to plaintiffs' claims because, to affect competition, Reckitt's statements would have had to persuade "medical professionals, that is, persons knowledgeable of the subject matter" and thus unlikely to be deceived. (DP Reply at 20 (quoting *Walgreen Co. v. AstraZeneca Pharm. LP*,

534 F. Supp. 2d 146, 152 (D.D.C. 2008)).) Moreover, any alleged fraudulent statements regarding safety could have been easily countered by the generics. (Instead, the generics themselves have also switched to using unit-dose packaging. *See* Exh. B.) Thus, this Court should grant Reckitt's motion, apply the *de minimis* presumption, and dismiss Count II.

For the foregoing reasons, this Court should consider the three arguments that were not addressed in the Court's opinion, and the new evidence that was unavailable at the time of Reckitt's motion (and indeed, the oral argument on that motion). Each of these three issues raises a clear question of law, and each would greatly streamline the case going forward by eliminating claims or defendants.

ARGUMENT

I. THE PETITIONING CLAIMS SHOULD BE DISMISSED BECAUSE NEW EVIDENCE PROVES THE FDA DID NOT VIOLATE 21 U.S.C. § 355(q)(1)(A) AND, IN ANY EVENT, A HYPOTHETICAL VIOLATION WOULD CONSTITUTE A SUPERSEDING CAUSE

One of the novel issues addressed in this Court's December 3rd ruling is the interaction between 21 U.S.C. § 355(q) and a claim of sham petitioning. Congress enacted this statute in 2007 to end the very delay of which plaintiffs complain. Specifically, 21 U.S.C. § 355(q)(1)(A) *required* the FDA to consider Reckitt's Petition "separate and apart from review and approval" of the generic ANDAs, and *forbade* the FDA from delaying of ANDA approval "before and during" consideration of the Petition." *Id.*

Reckitt contended that this statute precluded plaintiffs from "plead[ing] causation" of their alleged injury. (DP Mot. at 30-33.) This causation argument consisted of two parts: (1) Plaintiffs failed to allege the FDA violated the statute, and (2) even assuming such a violation, Reckitt should not be held liable for the FDA's breach of its statutory duty. (DP Reply at 21.) In denying Reckitt's motion to dismiss, this Court rejected the first part of Reckitt's causation

argument. (Dkt. No. 97 at 33.) But new evidence—which only became available after oral argument—contradicts plaintiffs' allegation of a statutory violation by the FDA. Moreover, the Court did not discuss the second part of Reckitt's causation argument, that any FDA violation would constitute a superseding cause relieving Reckitt from liability.

A. New Evidence Subject To Judicial Notice Proves That The FDA Did Not Violate 21 U.S.C. § 355(q)(1)(A) In This Case

Although Reckitt maintains that plaintiffs did not allege that the FDA violated 21 U.S.C. § 355(q)(1)(A) in connection with Reckitt's Petition, it does not seek to reargue that point. Instead, Reckitt contends that this Court need not credit plaintiffs' claim of a violation, because any such allegation is contradicted by new facts subject to judicial notice. Specifically, on November 17, 2014, the FDA informed Congress that it had only delayed ANDA approvals in connection with one citizen's petition in fiscal year 2013. (*See* Exh. A.) That petition was not Reckitt's. It was Novartis's. (*Cf.* DP Mot., Exh. D.)

It is well-established that, in ruling on a 12(b)(6) motion, the Court need not credit allegations that contradict matters subject to judicial notice. *Hanover Ins. Co. v. Ryan*, 619 F. Supp. 2d 127, 133 (E.D. Pa. 2007); *see also, e.g.*, DP Mot. at 10 n.6, 11 (citing *In re Livent, Inc. Noteholders Sec. Litig.*, 151 F. Supp. 2d 371, 405-06 (S.D.N.Y. 2011)). It is equally well-established that agency reports to congress and official FDA documents are subject to judicial notice. *See Dodd v. Tenn. Valley Auth.*, 770 F.2d 1038, 1039 (Fed. Cir. 1985); *see also* DP Reply at 22 n.14. For these reasons, plaintiffs did not object to Reckitt's previous submission of the FDA's then-most recent annual report, the fourth, for purposes of its motion to dismiss. (*See* DP Mot., Exh. C.) The Court may therefore consider the fact and contents of the FDA's Sixth Annual Report, attached as Exhibit A, for purposes of this motion.

The FDA's report provides direct evidence that only one petition caused delay of ANDA

approvals in fiscal year 2013. (*See* Exh. A at 3.) Specifically, the report states that the "FDA's decision to delay approval of two pending ANDAs during this reporting period was based on the Agency's assessment that further review of the issues raised in *the 505(q) petition* was required." (*Id.* (emphasis on singular added).) Moreover, the FDA informed Congress that, in the history of 21 U.S.C. § 355(q), only six petitions had caused a delay of ANDAs. (*Id.* at 7; *compare* Mot., Exh. C at 3 (five petitions by FY2011, meaning there could be only one more between the Fourth Annual Report and the Sixth Annual Report).)

This Court already knows the identity of that one petition. (*See* Op'n at 33.) It was Novartis's, not Reckitt's. Indeed, the Sixth Annual Report confirms that it is discussing Novartis's petition by stating that the delay lasted "25 days." (Exh. A at 3; *cf.* DP Mot., Exh. D at 12 (stating that Novartis's petition caused 25-day delay).)

In sum, the FDA's Sixth Annual Report indicates that the FDA did not violate 21 U.S.C. § 355(q)(1)(A) by delaying approval of any ANDAs while considering Reckitt's petition. This Court need not credit any allegation to the contrary. Indeed, plaintiffs allege no non-conclusory fact to support the inference that, simply because the FDA *might* violate the statute (as it did in the case of the Novartis petition), the agency actually did so *in this case*. In light of the specific evidence to the contrary in the FDA's Sixth Annual Report, of which the Court may take judicial notice, no such inference is plausible under *Twombly*, 550 U.S. at 570.

B. In Any Event, The FDA's Violation Of Its Statutory Obligations Would Constitute A Superseding Cause

Even if the Court did choose to credit any allegation of a statutory violation despite the Sixth Annual Report, it would still need to address the second prong of Reckitt's causation argument. That argument maintains that "when an antitrust-plaintiff's injury is proximately caused by the government, the government's action constitutes a supervening cause that breaks

the chain of causation between an antitrust-defendant's action and any anticompetitive effect." *Mass. Sch. of Law*, 937 F. Supp. at 439 (E.D. Pa. 1996). Reckitt raised this point in both its briefs, but it remains unaddressed. (DP Mot. at 33 n.31; DP Reply at 21.)

Numerous courts—including this one—have held that actions of an independent governmental agency will sever the causal chain between an allegedly wrongful action and the plaintiff's injury.[1] *Barr Laboratories, Inc. v. Quantum Pharmics, Inc.*, 827 F. Supp. 111 (E.D.N.Y. 1993), is particularly instructive. In that RICO case,[2] as here, Barr alleged injury in the form of reduced generic sales as a result of Quantum's alleged fraud on the FDA in the form of a false ANDA. *Id.* at 116. Nonetheless, the court dismissed the complaint for failure to allege causation: "[Barr's] alleged losses do not stem from the allegedly false ANDA's filed with the FDA. Those losses depend on the intervening actions of the FDA and Quantum's customers. The FDA had discretion in deciding whether or not to issue the licenses to Quantum." *Id.*; *see also, e.g.*, *Dow Chem. Co. v. Exxon Corp.*, 30 F. Supp. 2d 673, 695 (D. Del. 1998) (dismissing RICO claim predicated on patent-procurement fraud for failure to allege causation: "The PTO has discretion whether or not to grant patent property rights and declare interferences and it is only those intervening decisions that connect Exxon's allegedly fraudulent misrepresentations to

[1] *See, e.g.*, *Galen v. County of Los Angeles*, 477 F.3d 652, 663 (9th Cir. 2007) ("[A] judicial officer's exercise of independent judgment in the course of his official duties is a superseding cause" breaking causal chain from alleged misconduct of law enforcement officer to excessive bail); *Townes v. City of New York*, 176 F.3d 138, 146-47 (2d Cir. 1999) ("The state trial court's exercise of independent judgment in deciding not to suppress the evidence, though later ruled to be erroneous, broke the chain of causation" from unconstitutional search to wrongful conviction); *Exxon Corp. v. Amoco Oil Co.*, 875 F.2d 1085, 1089 (4th Cir. 1989) (reversing denial of judgment as a matter of law for negligence defendant because of superseding "arbitrary act[] of government bureaucracy"); *Midland Export, Ltd. v. Elkem Holding, Inc.*, 947 F. Supp. 163, 166 (E.D. Pa. 1996) (finding lack of antitrust standing because ITC's "independent determination" was "the direct cause of the harm alleged here").

[2] The Third Circuit has recognized the relationship between antitrust and RICO causation principles. *See Anderson v. Ayling*, 396 F.3d 265, 270 (3d Cir. 2005).

the losses suffered by Dow.").

As *Dow Chemical* and *Massachusetts School of Law* show, Reckitt's superseding causation argument is fully consistent with Third Circuit law. Indeed, in *Egervary v. Young*, 366 F.3d 238 (3d Cir. 2004), that court itself held that a government actor's "fail[ure] to properly apply the governing law and procedures . . . must be held to be a superseding cause." *Id.* at 251.

Moreover, unlike the governmental actors in *Massachusetts School of Law*, *Barr*, or *Egervary*, the FDA had no discretion here. 21 U.S.C. § 355(q)(1)(A) expressly forbids the agency from delaying ANDA approval. *A fortiori*, the FDA's independent decision to violate its statutory duty constitutes a superseding cause. Reckitt had the right to expect that the government would follow the law. *Cf., e.g.*, *Bialek v. Mukasey*, 529 F.3d 1267, 1274 (10th Cir. 2008) ("We expect that FEC commissioners, like any other government officials, follow the law.").

In sum, 21 U.S.C. § 355(q)(1)(A) serves two purposes. Most obviously, it protects generic drug makers and the public by ensuring that citizen's petitions will not delay ANDA approval. But it also protects the First Amendment rights of branded companies by ensuring that they can petition the government without the specter of being accused of causing delay. If the FDA chose to violate its statutory obligations when considering Reckitt's Petition, that decision would constitute a superseding cause which would relieve Reckitt from liability on Counts IV-V.

Accordingly, this Court should grant Reckitt's motion so it can give proper consideration both to the new evidence and to the second prong of Reckitt's causation argument.

II. RECKITT BENCKISER GROUP, plc SHOULD BE DISMISSED BECAUSE THE END-PAYOR PLAINTIFFS FAILED TO ALLEGE THAT IT POSSESSED MARKET POWER

This Court's December 3rd ruling correctly noted that only Reckitt "actually sells Suboxone" in the alleged geographic market of the United States. (Op'n at 73.) Yet, in addition

to Reckitt, plaintiffs asserted claims against four other Reckitt entities. Reckitt moved to dismiss those additional entities. (EP Mot. at 38-39; EP Reply at 24.) This Court granted Reckitt's motion as to three of the entities entirely and also dismissed the direct purchasers' claims against the fourth, Reckitt Benckiser Group, plc ("RBG"). But the Court declined to dismiss the end-payors' claims against RBG. (Op'n at 73-74.)

In so doing, the Court overlooked a key part of Reckitt's motion. The Court described Reckitt as contending that the end-payors had "fail[ed] to identify what *role*, if any, [RBG] played in the alleged anticompetitive scheme." (*Id.* at 73 (emphasis added).) To be sure, Reckitt did argue that plaintiffs failed to allege specific actions by RBG. (EP Mot. at 38; EP Reply at 24 ("[P]laintiffs failed to allege either market power *or exclusionary conduct*." (emphasis added)).). But Reckitt also argued that, even if a specific anticompetitive action or role was alleged, the complaints said nothing "relate[d] to [RBG's] *market power*." (EP Reply at 24 (emphasis added); *see also* EP Mot. at 38-39.) This Court did not consider Reckitt's separate market power theory, and so should grant reconsideration to address it now.

If it does so, the Court will find that dismissal of RBG is necessary. As the Court correctly noted, a traditional § 2 claim consists of two elements: (1) market power and (2) exclusionary conduct. (Op'n at 12 (quoting *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966)).) The end-payor's allegations concerning RBG's *role*, which the Court deemed sufficient, would address only the second element.

Nothing in the end-payors' complaint speaks to the first element of its § 2 claims against RBG, *market power*. The lack of any such allegations is hardly surprising. RBG has no power in the markets alleged here. It is not approved to sell, and does not sell, Suboxone in the United States. (EP Reply at 24-25.) The end-payors make no argument and, more importantly, no

allegation of fact to the contrary.

The end-payors cannot save their § 2 claims against RBG by referencing *Reckitt's* market share. As this Court noted (Op'n at 73 n.31), the law is plain that an antitrust plaintiff must allege the required elements of a § 2 claim against each individual defendant. *See In re Mushroom Direct Purchaser Antitrust Litig.*, 514 F. Supp. 2d 683, 699 (E.D. Pa. 2007) ("In order to sustain their claims of monopolization and attempted monopolization, Plaintiffs must . . . prove the required elements against each individual defendant.") (quoting *Carpet Group Int'l v. Oriental Rug Imps. Assoc.*, 256 F. Supp. 2d 249, 284 (D.N.J. 2003)); *see also In re Digital Music Antitrust Litig.*, 812 F. Supp. 2d 390, 417 (S.D.N.Y. 2011); *Santana Products, Inc. v. Sylvester & Assocs.*, 121 F. Supp. 2d 729, 741 (E.D.N.Y. 1999) (collecting cases rejecting allegations of "shared monopoly").

Nor could the end-payors avoid dismissal by recasting their claims as addressed to a § 2 conspiracy to monopolize. Not only does their complaint nowhere mention the word conspiracy, but such allegations would be legally irrelevant even if made. Thirty years ago, the Supreme Court decided that a parent company (such as RBG) and its wholly-owned subsidiary (Reckitt) "are incapable of conspiring with each other." *Copperweld Corp.*, 467 U.S. at 777.[3]

In sum, market power is an additional necessary element of the end-payor's § 2 claims

[3] Although *Copperweld* was a § 1 case, its prohibition of intra-corporate antitrust conspiracies applies equally to § 2 conspiracy claims. *See, e.g.*, *Surgical Care Center of Hammond, L.C. v. Hosp. Serv. Dist. No. 1 of Tangipahoa Parish*, 309 F.3d 836 , 840-41 (5th Cir. 2002) (conspiracy to monopolize claim barred because "as a matter of law, a corporation and its agent . . . are incapable of conspiring with one another to violate the antitrust laws"); *Vollrath Co. v. Sammi Corp.*, 9 F.3d 1455, 1463 (9th Cir. 1993) (dismissing, under *Copperweld*, both section 1 and section 2 conspiracy claims among related corporations); *H.R.M., Inc. v. Tele-Communications, Inc.*, 653 F. Supp. 645 , 648 (D. Colo. 1987) ("[A] claim under section 2 for conspiracy to monopolize, like a claim under section 1 , requires at least two participants. Therefore, the Court's rationale in the Copperweld decision . . . also applies to foreclose a claim of conspiracy to monopolize under section 2 of the Sherman Act."); *see generally* Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 809.

that they must plead and prove with respect to RBG just as they have done with Reckitt. But the end-payors have not alleged any facts about RBG's market power, likely because it has none. RBG is therefore entitled to dismissal. This Court should grant reconsideration to address Reckitt's market power argument and dismiss the end-payors' claims against RBG.

III. THE PRODUCT-HOP CLAIMS SHOULD BE DISMISSED BECAUSE PLAINTIFFS FAILED TO ALLEGE FACTS SUFFICIENT TO OVERCOME THE PRESUMPTION THAT RECKITT'S STATEMENTS HAD A *DE MINIMIS* EFFECT ON COMPETITION

The Court agreed with the major premise of Reckitt's product-hopping argument, that "introducing a new product on the market, *whether it is a superior product or not*, does not, by itself constitute exclusionary conduct." (Op'n at 18 (emphasis added).) Nonetheless, the Court declined to dismiss Count II because of Reckitt's alleged "'coercive' measures," namely Reckitt's statements to the market regarding its intention to withdraw tablets due to safety concerns. (*Id.* at 19 (discussing "[t]he threatened removal of the tablets from the market in conjunction with the alleged fabricated safety concerns").) In so doing, however, the Court did not mention Reckitt's argument concerning the "strong presumption that statements by competitors have a '*de minimis*' effect on competition." (DP Reply at 19; *see id.* at 12 & n.6 (cross-referencing this argument); DP Mot. at 18.) This Court should grant reconsideration to address this presumption.

Where a § 2 claim is based on "false disparagement of a product," (Op'n at 18), other "courts have applied a presumption of *de minimis* harm to competition. . . . To overcome the presumption . . ., a plaintiff must show that the representations 'were [1] clearly false, [2] clearly material, [3] clearly likely to induce reasonable reliance, [4] made to buyers without knowledge of the subject matter, [5] continued for long periods, and [6] not readily susceptible of neutralization or other offset by rivals.'" *Santana Products v. Bobrick Washroom Equip., Inc.,*

249 F. Supp. 2d 463, 517 n.47 (M.D. Pa. 2003) (quoting *Am. Prof'l Testing Serv., Inc. v. Harcourt Brace Jovanovich Legal & Prof'l Publ'ns, Inc.*, 108 F.3d 1147, 1152 (9th Cir. 1997)), *aff'd in relevant part on interlocutory appeal*, 401 F.3d 123, 132 (3d Cir. 2005).

Moreover, the *de minimis* presumption applies to the pleadings. *See Tate v. Pac. Gas & Elec. Co.*, 230 F. Supp. 2d 1072, 1080 (N.D. Cal. 2002) (granting Rule 12(b)(6) motion to dismiss because "Plaintiffs have not pled that the defendant's disparaging comments were clearly likely to induce reasonable reliance by the public or private clients, or that disparaging comments were made to buyers without knowledge of the subject matter, or that the violations were not readily susceptible of neutralization or other offsets by rivals" (emphases removed)). Indeed, Reckitt's primary case—*Walgreen*—applied this presumption to dismiss pharmaceutical product-hopping claims based on false disparagement. *Id.* at 151.

Here, plaintiffs' allegations cannot satisfy several of the elements necessary to overcome the *de minimis* presumption. ***First,*** Reckitt's statement that it intended to withdraw Suboxone tablets was not only not "clearly false," it was demonstrably *true* because Reckitt did, in fact, withdraw the tablets. Moreover, the law *required* Reckitt to give at least six months advance notice of its intention to withdraw tablets. *See* 21 U.S.C. § 356c ("A manufacturer of a drug that is . . . intended for use in the prevention or treatment of a debilitating disease . . . shall notify the Secretary . . . of a permanent discontinuance in the manufacture of the drug . . . and the reasons for such discontinuance . . . . at least 6 months prior to the date of the discontinuance . . . .").

Likewise, Reckitt's allegedly "fabricated" safety concerns are a classic example of a statement of opinion based on disclosed facts. It bears noting that the study demonstrating that the number of pediatric exposures was *eight times* lower with Suboxone film was accepted for publication in one of the leading peer-reviewed medical journals. *See* Eric J. Lavonas, M.D. *et*

al., *Root Causes, Clinical Effects, and Outcomes of Unintentional Exposures to Buprenorphine by Young Children*, 163 J. Peds. 1377 (2013). Moreover, while plaintiffs contend that Reckitt's emphasis on the importance of unit-dose packaging was contrived, the manufacturers of generic Suboxone tablets have since requested the FDA's permission to utilize that packaging themselves. *See* Exh. B;[4] *see also* Maribeth C. Lovegrove *et al.*, *Emergency Hospitalizations for Unsupervised Prescription Medication Ingestions by Young Children*,134 Pediatrics 1009, 1014 (2014) (noting decision by generic Suboxone tablet manufacturers to switch to unit-dose packaging). In sum, whatever the ultimate merits of Reckitt's opinion on safety, plaintiffs have not alleged facts sufficient to show that it was "clearly false."

***Second*,** plaintiffs likewise cannot show that Reckitt's statements regarding its intention to withdraw Suboxone tablets were "clearly material." According to plaintiffs, Reckitt announced its intention in September 2012. (Dkt. No. 47 ('DP Compl.') at ¶ 93.) But, by that time, a majority of Suboxone consumers had already switched to the film product. (*Id.* at ¶ 92.)

***Third*,** plaintiffs' own allegations concerning the prevalence of supposed product-hopping schemes (*see, e.g.*, DP Compl. ¶¶ 51-52, 56), and sham petitions within the pharmaceutical industry (*see, e.g.*, *id.* at ¶¶ 67-71), undercut any likelihood that Reckitt's alleged conduct would "induce reasonable reliance." If such conduct is as "well known in the pharmaceutical industry" as plaintiffs allege (*id.* at ¶ 71), then participants in the industry would know to carefully scrutinize a branded drug manufacturer's disparagement of an older product in favor of its newer version. That is particularly true where, as here, there was *never* a time when

[4] As with Exhibit A, the documents attached within Exhibit B are subject to judicial notice as official FDA documents available from the FDA website. *See, e.g.*, http://1.usa.gov/1yDh1TQ. Moreover, these documents are also new evidence that was not previously available at the time Reckitt submitted its motion or reply, as their dates (April and May 2014) indicate.

a doctor or a patient did not have the choice of a tablet when considering Suboxone film.

***Fourth*,** plaintiffs do not and cannot allege that Reckitt's statements were "made to buyers without knowledge of the subject matter." Doctors and medical professionals—the primary alleged targets of Reckitt's supposed disparagement (*see id.* at ¶ 89)—are necessary knowledgeable in the subject matter of medicine. This fact proved dispositive in *Walgreen*'s rejection of similar product disparagement allegations: "Plaintiffs cannot hope to make such a showing [necessary to overcome the *de minimis* presumption] because Nexium sales necessarily depended on prescriptions written by medical professionals, that is, persons knowledgeable of the subject matter." 354 F. Supp. at 151. The only difference between the allegations of product disparagement in *Walgreen* and this case is that Plaintiffs allege that Reckitt announced its intention to withdraw Suboxone tablets—a statement which, as discussed above, is unquestionably true.

***Finally*,** and most tellingly, plaintiffs also do not and cannot allege that the generic manufacturers were incapable of "neutraliz[ing]" Reckitt's alleged disparagement. As Reckitt contended in its reply brief, such neutralization would be simple: the generics would only need to counter Reckitt's statements by trumpeting the alleged safety benefits of tablets. (*See* DP Reply at 20 n.12 (citing *Innovation Ventures, LLC v. N.V.E., Inc.*, 694 F.3d 723, 741-42 (6th Cir. 2012) (the ability to counter marketing with marketing shows that false advertising is not difficult to overcome)).) Indeed, the end-payors *conceded* that the generics were capable of such neutralization, but argued that they lacked an incentive to do so prior to receiving FDA approval. (*See* Dkt. No. 68 at 6-7.) But plaintiffs cannot have it both ways. Either the generics are competitors with an incentive to compete, or they are not. If the generics are competitors, then they had both the incentive and the means to neutralize Reckitt's alleged disparagement.

In sum, the seminal antitrust case on product innovation warned that "[b]efore we would allow misrepresentations to buyers to be the basis of a competitor's treble damage action under § 2, we would ***at least*** require the plaintiff to overcome a presumption that the effect on competition of such a practice was *de minimis*." *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 288 n.41 (2d Cir. 1979) (emphasis added). Reckitt clearly raised this presumption in both its opening and reply brief. (*See* DP Mot. at 18; DP Reply at 12 n.6 (incorporating argument set forth on pages 19-21).) This Court should grant Reckitt's motion for reconsideration, address this argument, and dismiss Count II.

CONCLUSION

For the foregoing reasons, Reckitt respectfully requests that the Court grant its motion for reconsideration. In addition, Reckitt requests that the Court resolve this motion prior to issuing further deadlines for any amended complaints and answers. (*See* Pretrial Order No.2, Dkt. No. 44 at 5, § 6(g) ("All further deadlines shall be set upon disposition of the above motions.").) The Direct Purchaser plaintiffs have indicated an intention to amend their complaint (which the Court "urge[d]" them to do), (*see* Op'n at 70 n.29, 72 n.30), this Court's December 3 opinion has eliminated certain claims and defendants from the case, and the Court's decision on this motion may eliminate more. *See Jackson v. Rohm & Haas Co.*, No. 06-3682, 2007 BL 108926, at *2 (E.D. Pa. Sept. 26, 2007) (deferring proceedings after partial dismissal pending amendment to the complaint). Reckitt therefore also requests that the Court schedule these deadlines after resolution of this motion.

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Respectfully submitted,

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